UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In Re Pharmaceutical Industry Average Wholesale Price Litigation,	No. MDL Docket No. 1456 CIVIL ACTION: 01-CV-12257-PBS
This Document Relates to The Master Consolidated Class Action	Judge Patti B. Saris **FILED UNDER SEAL** **REDACTED VERSION**

SICOR INC.'S INDIVIDUAL MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO CERTIFY CLAIMS WITH RESPECT TO TRACK 2 DEFENDANTS

INTRODUCTION

Plaintiffs' allegations encompass Sicor Inc., f/k/a Gensia, Inc. and Gensia Sicor Inc.,[1] ("the Sicor Group" or "Sicor") and eight generic drugs that have, over time, been manufactured by Sicor (among other Track 2 Defendants): (1) Acyclovir Sodium; (2) Amikacin Sulfate; (3) Amphotercin B; (4) Doxorubicin HCL; (5) Etoposide; (6) Leucovorin Calcium; (7) Pentamidine Isethionate (Pentacarinat); and (8) Tobramycin Sulfate ("Subject Drugs"). These 8 drugs are the only Subject Drugs that plaintiffs identify as having been manufactured by the Sicor Group.[2]

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[1] Plaintiffs refer to Gensia, Inc. (1993), Gensia Sicor (1997), and Sicor Inc. (1999), as "The Sicor Group."

[2] See Revised Appendix A to FAMCC, p. 16 (Gensia) and pp. 20-21 (Sicor), and Table of Subject Drugs attached to Plaintiffs' [Proposed] Consolidated Order re: Motion for Class Certification Track 2, p. 15 (Gensia) and p. 19 (Sicor).

Though the Fourth Amended Master Consolidated Class Action Complaint ("FAMCC") and Plaintiffs' Memorandum of Law in Support of Motion to Certify Claims with Respect to Track 2 Defendants ("Pl. Mem.") contain allegations regarding additional drugs manufactured by the Sicor Group, none of those "new drugs" are at issue in this litigation, since they are deemed to have been stricken by the Court's April 13, 2006 Order.

As set forth below, plaintiffs have failed to establish that the proposed representatives for Classes 1 and 3 ever paid for any of the Subject Drugs manufactured by the Sicor Group. With respect to Class 2, plaintiffs have failed to demonstrate that the proposed representative made payments based on AWP for a drug manufactured by Sicor. For these reasons, there is no basis for the Court to certify any subclass against the Sicor Group.[3]

I. Plaintiffs Have Failed to Identify a Typical Representative for Any of the Sicor Subclasses

Plaintiffs cannot satisfy the most fundamental typicality requirement of Rule 23 because they have failed to demonstrate that any of the proposed representatives are, in fact, a part of the putative subclasses they seek to represent.

A. A Class Representative Must Be in the Class He Seeks to Represent, and None of the Proposed Class Representatives Is a Member of His Respective Sicor Group Subclass.

1. Plaintiffs Failed to Demonstrate that the Proposed Class 1 Representative Is a Member of the Sicor Group Subclass.

The only proposed Class 1 representative for the Sicor Class 1 Subclass is Roger Clark, who is the representative of the Estate of David Clark, his father. Plaintiffs have failed to proffer any evidence that David Clark paid for any of the Sicor drugs at issue. Accordingly, neither Roger Clark nor the Estate of David Clark can be an adequate or typical representative, and there is no basis for the Court to certify a Sicor Subclass for Class 1.

In the FAMCC, David Clark is alleged to have made payments based on AWP for only one of the Sicor Subject Drugs during the relevant period: [redacted]. (FAMCC, ¶ 17.)[4]

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[3] Sicor incorporates the Track 2 Defendants' Joint Memorandum in Opposition to Plaintiffs' Motion to Certify Claims with Respect to Track 2 Defendants and the Expert Report, as well as the individual briefs filed on behalf of each of the Track 2 Defendants.

[4] There is no evidence to support this claim. Plaintiffs produced only one document from Mr. Clark's files that references [redacted] (Exhibit 1, Clark 0285). That document shows that the drug administration date was [redacted], more than [redacted] after the January 1, 2005 cut-off for the class period. (The class period

However, Plaintiffs appear to have abandoned this allegation, as there is no mention of [redacted] in the portions of the Haviland Declaration that relate to Mr. Clark's claim. (See Haviland Dec. ¶¶ 21-30.)

In their class certification brief, plaintiffs make the general allegation that the Haviland Declaration establishes that Mr. Clark "paid for drugs manufactured by Baxter, Fujisawa, Sicor and Watson." (Pl. Mem. at 2-3.) However, the Haviland Declaration addresses only two drugs prescribed to Mr. Clark: [redacted] and [redacted]. (Haviland Dec. ¶ 23.)

Neither [redacted] nor [redacted] are among the Subject Drugs identified for the Sicor Group. Pursuant to the Court's April 13, 2006 Order, all "new drugs" have been stricken, and, accordingly, plaintiffs are precluded from including these two drugs in the Sicor Group subclass of Class 1.[5]

Because [redacted] and [redacted] are not drugs at issue for the Sicor subclass of Class 1, and because plaintiffs have failed to establish that Mr. Clark was administered any Subject Drug manufactured by Sicor within the applicable class period, neither Mr. Clark, nor his estate, can be a member of the proposed Sicor subclass.

2. Plaintiffs Failed to Demonstrate that the Proposed Class 3 Representative Is a Member of the Sicor Subclass.

The only Class 3 representative proposed for the Sicor subclass is Pipefitters Local 537 Trust Funds ("Pipefitters"). The plaintiffs have failed to demonstrate that Pipefitters paid for any drug that was manufactured by the Sicor Group.

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is identified in Plaintiffs' [Proposed] Consolidated Order re: Motion for Class Certification Track 2 at page 5. See also Consolidated Order re: Motion for Class Certification [Track 1], dated Jan. 30, 2006.)

[5] The Young Declaration, June 15, 2006, ¶ 78 and the accompanying Exhibit 7, ¶¶ 12 - 13, incorrectly makes reference to [redacted] and [redacted] as Sicor Subject Drugs, they are not. The only Sicor Subject Drug at issue for David Clark is [redacted]. See Revised Appendix A to FAMCC.

In their class certification brief, plaintiffs claim that "Pipefitters has paid for drugs manufactured by all Track 2 Defendants except Pfizer and Gensia," which also includes Sicor and Gensia Sicor. (Pl. Mem. p. 3.) Plaintiffs rely on the Hannaford Declaration to support this allegation. However, nothing in the Hannaford Declaration suggests that Pipefitters made payments for any drug manufactured by Sicor. In fact, paragraph 7 of the Hannaford Declaration (as well as Exhibit 1 to that declaration) specifically identifies ten of the Track 2 Defendants that allegedly manufactured drugs for which Pipefitters made payments, and the Sicor Group is not among them.[6] For all intents and purposes, plaintiffs have conceded that Pipefitters is not a member of the Class 3 Sicor subclass.

3. Plaintiffs Have Failed to Demonstrate that the Proposed Class 2 Representative Paid for Drugs Manufactured by Sicor.

The only plaintiff proposed as a representative of Class 2 against Sicor Group is the Sheet Metal Workers National Fund ("Sheet Metal"). (Pl. Mem. p. 3.) Notably, plaintiffs have failed to allege that Sheet Metal paid for any Subject Drug that was actually manufactured by Sicor. Instead, plaintiffs suggest only that this is a possibility, alleging that Sheet Metal made payments for drugs that "**may have been** manufactured and sold" by the Sicor Group. (Randle Aff. ¶ 6 (emphasis added).)

The Randle Affidavit identifies the type of drugs for which Sheet Metal allegedly paid reimbursements based on AWP, without making any attempt to identify the actual manufacturer of the drug. Two of these drugs – doxorubicin and leucovorin calcium – are drugs included in the list of Sicor Subject Drugs. (See Ex. 2 to Randle Aff.) Plaintiffs acknowledge that doxorubicin and leucovorin calcium are multi-source drugs which are manufactured by at least

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[6] The ten Track 2 Defendants identified in the Hannaford Declaration are: Abbott, Amgen, Aventis, Bayer, Baxter, Dey, Fujisawa, Immunex, Pharmacia, and Watson. (Hannaford Dec. ¶ 7; see also Ex. 1 to Hannaford Dec.)

five companies other than Sicor, and plaintiffs have not made any attempt to identify the specific manufacturer of the drugs paid for by Sheet Metal.

Sheet Metal has undeniably failed to demonstrate that it is a member of the Class 2 Sicor subclass.

4. Because the Proposed Representatives for Classes 1, 2 and 3 Are Not Members of the Class They Seek to Represent, the Court Must Deny Certification of Classes Against Sicor.

As the United States Supreme Court "has repeatedly held, a class representative must be part of the class and 'possess the same interest and suffer the same injury' as the class members." East Texas Motor Freight System, Inc. v. Rodriguez, 431 U.S. 395, 403 (1977) (emphasis added) (reversing Fifth Circuit's certification of class in which named plaintiffs were not members of the class). Because none of the proposed representatives for Classes 1, 2 or 3 have demonstrated that they are part of the class they seek to represent, this Court need look no further to deny plaintiffs' motion to certify claims on behalf of subclasses against the Sicor Group.

II. Even if the Court Were to Hold that the Proposed Class 2 Representative Need Not Identify the Precise Manufacturer of the Subject Drug, Individual Issues Preclude Certification

A. The Structure of the Generic Drug Market Necessitates Transaction-by-Transaction Analysis of Causation and Injury

The Sicor drugs at issue in this litigation are all multi-source drugs. As a result, proving that a particular individual or third-party payor paid for a Subject Drug that the Sicor Group specifically manufactured on the basis of a Sicor-specific AWP would require the sort of complicated, painstaking transaction-by-transaction investigation that totally precludes any class-wide resolution of the plaintiffs' claims.

For multi-source drugs, third-party payors do not usually reimburse on the basis of AWP. (See Report of Independent Expert Professor Ernst R. Berndt to Judge Patti Saris ("Berndt

Report"), ¶¶ 55-57; Young Decl. ¶ 10 (June 15, 2006).) When multi-source drug reimbursement is linked to AWP, it is often linked to the median AWP or the "lowest branded" AWP, not a manufacturer-specific AWP. (See Young Decl., ¶¶ 12, 38 (June 15, 2006); [Track 1] Gaier Report, ¶ 69 (October 25, 2004).) Discovering those exceedingly few, if any, instances when a payor's reimbursement was based not just on AWP, but on a Sicor-specific AWP, would entail an individualized multi-step examination of the contract and other documents associated with each multi-source drug transaction. (See Young Decl. ¶ 39 (June 15, 2006).)

Most importantly, even if the plaintiffs' scanty evidence is deemed sufficient to show that Sheet Metal paid for doxorubicin and/or leucovorin calcium on the basis of an AWP, it is impossible to tell what company manufactured those drugs. A single J-code typically covers all NDCs from all manufacturers that sell a particular multi-source drug, so neither consumers nor third-party payors know which manufacturer's version of a multi-source drug was administered. (See Berndt Report, ¶ 195; Young Decl. ¶¶ 12, 35-36 (June 15, 2006).) The plaintiffs' documents themselves illustrate this overwhelming obstacle – the Randle Affidavit exhibits include exactly the same record pages for doxorubicin (J9000) and leucovorin calcium (J0640), regardless of the particular defendant to which the exhibit relates. (See Randle Aff. Exhs. 3(a) (Abbott), 3(d) (Baxter), 3(h) (Fujisawa), 3(k) (Pharmacia), and 3(m) (Sicor).) Only a close scrutiny of each individual provider's purchase and inventory records might possibly reveal whether any given Subject Drug was manufactured by the Sicor Group, another defendant, or even a non-defendant.

In the final analysis, the intensely individual issues of causation and injury that this litigation raises are incapable of class-wide resolution, and class certification, especially as to the Sicor Group, should be denied.

CONCLUSION

For all the above reasons, this court should decline to certify any Class 1, 2 or 3 class representative for Sicor and accordingly should dismiss this lawsuit.

Respectfully submitted,

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Dated: June 15, 2006

CERTIFICATE OF SERVICE

I hereby certify that I, Elizabeth I. Hack, an attorney, caused a true and correct copy of the foregoing Sicor Inc.'s Redacted Individual Memorandum in Opposition to Plaintiffs' Motion to Certify Claims with Respect to Track 2 Defendants to be served on all counsel of record electronically via LexisNexis File & Serve system on July 7, 2006 pursuant to Section D of Case Management Order No. 2.

/s/ Elizabeth I. Hack
ELIZABETH I. HACK